



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

#### **FOR FURTHER INFORMATION CONTACT:**

Dianca Finch, Ph.D., 240-669-5503; [dianca.finch@nih.gov](mailto:dianca.finch@nih.gov). Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

#### **SUPPLEMENTARY INFORMATION:**

Technology description follows:

#### **Identification of a New Human Monoclonal Antibody that More Potently Prevents Malaria Infection**

##### **Description of Technology:**

Malaria is a major disease caused by a parasite transmitted through the bite of infected female mosquitoes. Globally, an estimated 214 million cases of malaria and 438,000 deaths from malaria occur annually, with children in African and South Asian

regions being most vulnerable. Approximately 1,500-2,000 cases of malaria are reported in the United States each year, mostly in returning travelers from malaria-endemic countries. Among the international travelers, military personnel, diplomats, pregnant women, children and older individuals with weakened immune systems are more likely to be at risk of malaria infection and mortality.

Currently, there is no licensed vaccine against *Plasmodium falciparum*, the deadliest species of malaria parasites. Antibodies can prevent malaria infection by binding to sporozoites, the infectious form of *P. falciparum* that is transmitted to humans by the bites of infected mosquitoes. The major target of anti-sporozoite antibodies is the *P. falciparum* circumsporozoite protein (PfCSP), an abundant surface protein on sporozoites that is essential for infecting liver cells, which is the critical step for initiating a productive infection. PfCSP is comprised of an N-terminal domain, a central region and the C-terminal region.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) have isolated a new neutralizing recombinant human monoclonal antibody, L9, from a protected volunteer immunized with whole *Plasmodium falciparum* sporozoites. L9 is notable for targeting PfCSP, the immunodominant immunogen that coats the surface of the sporozoite, specifically the Plasmodium infectious form injected into the human host by the mosquito. Also, in vivo studies in a mouse model of malaria infection demonstrated that L9 is more potent than CIS43, another antimalarial mAb, at preventing malaria infection.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

**Potential Commercial Applications:**

- A passive vaccine candidate to prevent and eradicate malaria.

**Competitive Advantages:**

- L9 may represent a more attractive passive vaccine candidate to advance through clinical testing and could yield a product superior to other vaccine candidates due to potency and preferential binding to unique epitopes on PfCSP.
- L9 may result in more durable protection than other vaccine candidates.

**Development Stage:** Preclinical Research.

**Inventors:** Robert Alan Seder(NIAID); Lawrence Tsuchun Wang(NIAID); Rachel Marie Vistein(NIAID); Joseph Richard Francica(NIAID).

**Publications:** Wang, L. T., *et al* (2020). A Potent Anti-Malarial Human Monoclonal Antibody Targets Circumsporozoite Protein Minor Repeats and Neutralizes Sporozoites in the Liver. *Immunity*.

**Intellectual Property:** HHS Reference Number E-087-2019 includes PCT Patent Application Number PCT/US2020/031345 filed on 05/04/2020.

**Licensing Contact:** To license this technology, please contact Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov.

Dated: November 6, 2020.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

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